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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,567	04/05/2002	Jonathan Richard Anthony Roffey	040283-0196	4959

7590 09/29/2003

Bernhard D Saxe
Foley & Lardner
Washington Harbour
3000 K Street N W, suite 500
Washington, DC 20007-5143

EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,567	ROFFEY ET AL	
	Examiner	Art Unit	
	Rebecca L Anderson	1626	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-21, 24-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-14, 17, 24, 25 and 28-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 IDS</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1-14 and 17-21 and 24-26 and 28-30 are currently pending in the instant application. New claim 30 was added in the amendment filed 7 July 2003. Claims 1-14, 17, 24, 25, 28, 29 and 30 are objected and claims 18-21 and 26 are withdrawn as being for non-elected inventions.

Election/Restrictions

Applicant's election with traverse of a Group drawn to a product of the formula (I) wherein:

R1-R5 are as found in claim 1, R6 and R7 are independently selected from hydrogen and alkyl and A is 2,3-dihydrofuryl, a process for the preparation of the product of formula (I) and a method of treatment (caring for or dealing with medically) of obesity in the response and amendment filed 7 July 2003 is acknowledged. The traversal is on the ground(s) that the reference cited by the examiner, US Patent No. 5,633,276 to support a finding of lack of unity of invention does not actually support such a finding. Specifically applicant states that the structural feature of the present claims is an indoline group substituted at its nitrogen atom by an aminoethyl group $-(CH_2)(CHR_3)_pNR_1R_2$, wherein R3 is alkyl and R1 and R2 are H or alkyl. Furthermore applicant states that US'276 does not allow for the second carbon atom in the side chain to be substituted and requires one of the substituents on the amino to be COR6. In response, the examiner points out that the structural feature present in the claims is N-aminoethyl indoline which is found in US'276. Although the variables on the N-aminoethyl indoline differ from US'276, they are not considered part of the

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technical feature present in the instant claims. Therefore, for essentially the same reasons as found in the previous office action, the claims herein lack unity of invention because the structural feature present in the claims is not a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. Also, even if the structural feature present in the claims was the indoline group substituted at its nitrogen atom by an aminoethyl group $-(CH_2)(CHR_3)_pNR_1R_2$, wherein R_3 is alkyl and R_1 and R_2 are H or alkyl, this would still not be considered a special technical feature which describes a contribution over the prior art as US Patent No. 5,755,829 discloses N-substituted 4-hydroxyindoline compounds wherein R_1 can be a (C1-4) aminoalkyl radical in which the amine is nono- or disubstituted by a (C1-4)alkyl group and the (C1-C4) alkyl group can be linear or branched (column 2, lines 5-51).

Applicants also argue that in regards to the R_6 and R_7 groups, the examiner has not shown that there is a lack of unity problem between the various possibilities for R_6 and R_7 or that searching of these extra groups would be a serious burden. In response, firstly, for essentially the same reasons as stated in the prior office action, the lack of unity has been shown by the fact that the technical feature, the N-aminoethyl indoline, in common with all of the instant claims is known in the prior art and is therefore not a special technical feature which defines a contribution over the prior art. Furthermore, since the claims lack unity of invention, the examiner may determine the groups of inventions which are so linked as to form a single general inventive concept without regard

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to whether the inventions are claimed in separate claims or as alternatives within a single claim. In this regard, the MPEP states in section 1850 D, that

wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (C) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains

The alternatives in R6 and R7 do not have a common property or activity as a hydrogen atom is not expected to react in the same way as a carbonitrile.. The alternatives also do not share a common structure, i.e. there is not common structure between hydrogen, alkylamino, alkylsulfonyl, etc., and the alternatives do not belong to a recognized class of chemical compounds in the art to which the invention pertains, specifically, the classification of hydroxy, carbonitrile, etc. differs in the US classification system.

Also, The inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database

search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Finally, applicants argue that in regards to the method of treatment claims, all of the conditions are linked by a single mechanism as shown by the attached journal articles in Appendix II. However again, for essentially the same reasons as stated in the prior office action, it is stated that the structural feature that found in all the claims is the N-aminoethyl indoline which is not a special technical feature that defines a contribution over the prior art of record and therefore the claims lack unity of invention. Furthermore, claims to different categories of invention are considered to have unity of invention if the claims are drawn only to one of the combinations listed in 37 CFR 1.475(b) (also listed on page 5 of the previous office action). Therefore the claims should be limited to only a product, a process for the manufacture of the said product, and a use (such as the treatment of obesity) of the said product.

The requirement is still deemed proper and is therefore made FINAL.

However, upon reconsideration and by request of applicant's representative the elected group for search and examination will be expanded to include the following as the elected group:

The product of the formula (I) wherein:

R1 and R2 are as found in claim 1,

R3 is as found in claim 1,

R4 and R5 are as found in claim 1,

R6 and R7 are as found in claim 1,

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A is 2,3-dihydrofuryl,

A process for the preparation of the product of the formula (I) and the methods of treatment (caring for or dealing with medically) of the disorders of the central nervous system selected from depression, atypical depression, bipolar disorders, anxiety disorders, obsessive-compulsive disorders, social phobias or panic states, sleep disorders, sexual dysfunction, psychoses, schizophrenia, migraine, pain, raised intracranial pressure, epilepsy, personality disorders, age-related behavioural disorders, behavioural disorders associated with demential, organic mental disorders, mental disorders in childhood, aggressivity, age-related memory disorders, chronic fatigue syndrome, drug and alcohol addiction, obesity, bulimia, anorexia nervosa and premenstrual tension.

Claim Objections

Claims 1-14, 17, 24, 25, 28, 29 and 30 are objected to for containing non-elected subject matter

The remaining subject matter of claims 7-14 and 16-19 that is not drawn to the above elected group stands withdrawn) as being for non elected subject matter. The remaining compounds and methods which are not within the elected group, which are independent and distinct from the elected group and do not have unity with the elected group because the technical feature present in the instant claims is not a special technical feature which defines a contribution over the prior art and are withdrawn from consideration. Compounds which are withdrawn are the compounds, for example, wherein: by means of a restriction requirement within the claim are, for example, the compounds wherein:

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A is , cyclohexenyl, cyclopentenyl, phenyl, dihydropyranyl, dihydrothienyl, tetrahydropyridinyl, 2,3-dihydro-1,4-dioxin, etc., and methods of treatment of damage to the central nervous system by trauma, stroke, neurodegenerative diseases or toxic or infective CNS diseases such as encephalitis or meningitis, thrombosis, gastrointestinal disorders such as gastrointestinal motility, diabetes insipidus, sleep apnea and conditions treatable by agonism of the 5HT₂ receptor except for depression, atypical depression, bipolar disorders, anxiety disorders, obsessive-compulsive disorders, social phobias or panic states, sleep disorders, sexual dysfunction, psychoses, schizophrenia, migraine, pain, raised intracranial pressure, epilepsy, personality disorders, age-related behavioural disorders, behavioural disorders associated with dementia, organic mental disorders, mental disorders in childhood, aggressivity, age-related memory disorders, chronic fatigue syndrome, drug and alcohol addiction, obesity, bulimia, anorexia nervosa and premenstrual tension, and methods of preventing disorders of the central nervous system, damage to the central nervous system, cardiovascular disorders, gastrointestinal disorders, diabetes insipidus, sleep apnea, etc.

Some specific species of the withdrawn compounds are the species of (S)-1-(benz[g]indolin-1-yl)-2-propylamine, (S)-1-(2,3,7,8-tetrahydrothieno[2,3-g]indol-1-yl)-2-propylamine, etc.

Claims 1-14, 17, 24, 25, 28, 29 and 30 drawn solely to the elected group identified supra in the election/restriction section as the group searched and examined would appear allowable over the prior art of record.

Conclusion

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

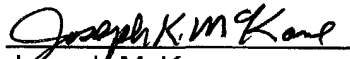
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600



Joseph McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600